

CLAIMS

What is claimed is:

1. A topical testosterone formulation comprising:
5 a modified poloxamer lecithin organogel carrier having admixed therein,
a therapeutically effective amount of an arginine ingredient,
a testosterone aromatization inhibiting amount of a tocopherol ingredient; and
an amount of micronized testosterone of from about 0.5% w/w to about 25%
w/w, wherein application of from about 0.5 g to about 2 g of the formulation to the
10 skin, produces physiologic testosterone serum levels in an individual having sub-
physiologic testosterone serum levels.
2. The formulation of claim 1, peak serum testosterone concentrations are
attained at about 24 to 36 hours after administration of the formulation.
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3. The formulation of claim 1, wherein the amount of arginine ingredient is from
about 0.1% w/w to about 20% w/w of the formulation.
4. The formulation of claim 3, wherein the amount of arginine ingredient is from
20 about 5% w/w to about 10% w/w of the formulation.
5. The formulation of claim 1, wherein the arginine ingredient is in a salt form.
6. The formulation of claim 5, wherein the arginine ingredient is L-arginine
25 monochloride.
7. The formulation of claim 1, wherein the amount of tocopherol is from about
0.1% w/w to about 20% w/w of the formulation.
- 30 8. The formulation of claim 7, wherein the amount of the tocopherol ingredient is
from about 5% w/w to about 10% w/w of the formulation.
9. The formulation of claim 1, wherein the tocopherol ingredient comprises
alpha tocopherol.

10. The formulation of claim 1, wherein the tocopherol ingredient comprises gamma tocopherol.

5 11. The formulation of claim 1, further comprising an effective amount of dehydroepiandrosterone (DHEA).

12. The formulation of claim 11, wherein the DHEA comprises dehydroepiandrosterone sulfate (DHEAS).

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13. The formulation of claim 11, wherein the amount of DHEA is about from about 1% w/w to about 20% w/w of the formulation.

14. The formulation of claim 1, further comprising an effective amount of
15 melatonin.

15. The formulation of claim 14, wherein the amount of melatonin is from about 1% w/w to about 20% w/w of the formulation.

20 16. The formulation of claim 1 further comprising an effective amount of progesterone.

17. The formulation of claim 16, wherein the amount of progesterone is from about 1% w/w to about 20% w/w of the formulation.

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18. The formulation of claim 1 wherein further comprising an effective amount of oxytocin.

19. The formulation of claim 18, wherein the amount of oxytocin is from about
30 1% w/w to about 20% w/w of the formulation.

20. The formulation of claim 1 wherein the amount of testosterone is from about 5% w/w to about 10% w/w, the amount of tocopherol is from about 5% w/w to about 10% w/w, and the amount of arginine is from about 5-10% of the formulation.

